Medtronic

LIFEPAK CR® PLUS

Defibrillator with ADAPTIV™ Biphasic Technology

Operating Instructions

CE
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OPERATING INSTRUCTIONS

LIFEPAK CR® PLUS

Defibrillator with ADAPTIV™ Biphasic Technology

IMPORTANT

This instrument is to be used by authorized personnel only.

!USA Rx only

!USA Device Tracking

The U.S. Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. The address to which this particular device was shipped is now listed as the current tracking location. If the device is located somewhere other than the shipping address or the device has been sold, donated, lost, stolen, exported, or destroyed, or if the device was not obtained directly from Medtronic, please either call the device tracking coordinator at 1.800.426.4448 or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

Responsibility for Information

It is the responsibility of our customers to ensure that the appropriate person(s) within their organization have access to this information, including general safety information provided in Section 1.

Revision History

These operating instructions describe LIFEPAK CR Plus Defibrillator with software version 3202124-003 or later.

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MIN 3201686-008 / CAT 26500-001361

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INTRODUCTION

This section provides background information about defibrillation and includes an overview of LIFEPAK CR® Plus Defibrillator features.

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ABOUT AUTOMATIC EXTERNAL DEFIBRILLATORS

The LIFEPAK CR Plus Defibrillator is an automated external defibrillator (AED). For many years, AEDs have been used only by medical professionals to treat patients in cardiac arrest. The ability of defibrillators to save lives is so widely recognized that people once trained to do only cardiopulmonary resuscitation (CPR) can now use them.

When electrode pads are applied to the patient's chest, the AED analyzes the patient's heart rhythm. If a shockable rhythm is detected, the AED will either deliver an intense pulse of electricity (shock) to the heart muscle (fully automatic model) or direct the responder to deliver the shock (semiautomatic model). The shocks are delivered through the electrode pads on the chest.

Delivery of this pulse of electricity is called defibrillation. Defibrillation is a recognized means of treating life-threatening irregularities of the heart beat, such as ventricular fibrillation, that cause cardiac arrest.

The LIFEPAK CR Plus Defibrillator is designed specifically for infrequent use and for use by people whose only training is in CPR and in using AEDs.

Indications for Use

The LIFEPAK CR Plus Defibrillator is indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). With Infant/Child Reduced Energy Defibrillation Electrodes, the LIFEPAK CR Plus Defibrillator may be used on children up to 8 years old or 25 kg (55 lb).

Contraindications

None known.

Why the Need for Defibrillators

The American Heart Association estimates that, in the USA alone, at least 250,000 people die each year of cardiac arrest. Of these, about 10,000 people might have been saved had they received immediate treatment from a defibrillator.

Cardiac arrest is usually caused by a malfunctioning of the heart's electrical system. Called ventricular fibrillation, this critical condition prevents the heart from pumping blood throughout the body. Ventricular fibrillation can cause death within seconds.

Defibrillation is a relatively simple procedure that involves placing electrode pads on a patient's exposed chest and delivering an electrical shock to the heart. The externally-delivered shock often restores the heart's electrical system to normal rhythm. Combined with CPR, defibrillation provides the most effective care for patients in cardiac arrest.

Terminology

The following terms appear in this manual.

AED	Automated External Defibrillator. A device that evaluates the patient's heart rhythm and delivers an electrical shock to the heart if a shockable rhythm is detected.
Cardiac arrest	The termination of the heart's pumping action resulting in the lack of a heartbeat or pulse and breathing.
CPR	Cardiopulmonary resuscitation. This involves delivering rescue breathing and chest compressions to a patient in cardiac arrest.
Defibrillation	Delivery of an electrical shock to the heart for the purpose of reversing ventricular fibrillation.
ECG	Electrocardiogram. A composite picture of what is occurring electrically in the heart.
Fibrillation	Chaotic activity of the heart's electrical system. This condition can occur in the atria or the ventricles. When it occurs in the ventricles, they quiver in a rapid, chaotic manner, preventing them from pumping blood to the body.
Heart attack	A nonspecific term referring to the death of heart muscle resulting from interruption of blood supply, often confused with cardiac arrest.
Impedance	Resistance to the flow of electrical current through the body.
Joule	The basic unit of energy delivered by a defibrillator.
LED	Light emitting diodes.
Myocardial infarction	The specific term for what is usually meant by heart attack; death of heart muscle resulting from an interruption of the blood supply to that area of myocardium.
Nonshockable rhythm	A heart rhythm that is detected by the defibrillator that does not need a shock, but may need CPR.
Patient	In this manual, the person suffering from cardiac arrest.
Responder	In this manual, the person giving aid to a patient in cardiac arrest. Used interchangeably with user.
SAS	Medtronic patented Shock Advisory System™.
Shockable rhythm	A heart rhythm that is detected by the defibrillator as requiring a shock, for example, ventricular fibrillation.
User	In this manual, the person giving aid to a patient in cardiac arrest. Used interchangeably with responder.
Ventricular fibrillation	A life-threatening chaotic heart rhythm.
Ventricular tachycardia	Rapid heart rhythm originating in the ventricle.

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Text Conventions

Throughout this manual, special text characters are used to indicate labels and voice prompts:

Operating control labels: CAPITAL LETTERS such as ON/OFF and SHOCK.

Voice prompts: *ITALICIZED CAPITAL LETTERS* such as *STAND CLEAR*.

SAFETY INFORMATION

This section provides important information to help you safely operate the LIFEPAK CR Plus Defibrillator. Take the time to familiarize yourself with all of the terms, warnings, and symbols presented in this section.

Safety Terms

You may encounter the following terms in this manual and while using the LIFEPAK CR Plus Defibrillator:

Danger	Immediate hazards that will result in serious personal injury or death to the user and/or the patient.
Warning	Hazards or unsafe practices that could result in serious personal injury or death to the user and/or the patient.
Caution	Hazards or unsafe practices that could result in minor personal injury to the user and/or the patient, product damage, or property damage.

General Warnings and Cautions

WARNINGS!

Shock hazard.

This defibrillator delivers up to 360 joules of electrical energy. Unless properly used as described in these operating instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Shock or fire hazard.

Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on the defibrillator or its accessories. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or the accessories unless otherwise specified.

Possible fire or explosion.

Do not use this defibrillator in the presence of flammable gases or anesthetics. Use care when operating this defibrillator close to oxygen sources (such as bag-valve-mask device or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

Possible device shutdown.

When the attention symbol ⚠ first appears on the readiness display, only a small number of shocks and monitoring time are available. Always keep a CHARGE-PAK™ in the defibrillator. Routinely check that the defibrillator is ready for use. Replace the CHARGE-PAK after each use of the defibrillator.

WARNINGS!

Possible electrical interference with device performance.

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in improper device operation, distorted ECG, failure to detect a shockable rhythm, or cessation of pacing. Avoid operating the device near cauterizers, diathermy equipment, cellular phones, or other portable and mobile RF communications equipment. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key EMS radios on and off. Contact a technical support representative if assistance is required.

Possible electrical interference.

Using cables, electrodes, or accessories not specified for use with this device may result in increased emissions or decreased resistance to electromagnetic interference which could affect the performance of this device or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

Possible electrical interference.

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. If possible, verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency situation.

Possible improper device performance.

Using other manufacturers' cables or electrodes may cause the defibrillator to perform improperly and invalidates the safety agency certification. Use only the parts and accessories specified in these Operating Instructions.

Safety risk and possible equipment damage.

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Skin burns will also occur due to heating of electrically conductive materials, such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.

Shock hazard.

Do not insert a finger or any object other than the CHARGE-PAK™ into the well of the defibrillator.

CAUTION!

Possible equipment damage.

This defibrillator may be damaged by mechanical or physical abuse, such as immersion in water or dropping the defibrillator. If the defibrillator has been abused, remove it from use and contact a qualified service technician.

Note: Medtronic Emergency Response Systems devices, electrodes, and cables are latex-free.

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SYMBOLS

The following symbols may appear in this manual and on the LIFEPAK CR Plus Defibrillator. For more information about the readiness display symbols, refer to Section 2, Getting Started.

Symbol	Explanation
OK	OK Indicator. The defibrillator is ready for use.
	Attention. On the readiness display—the internal battery is low. Refer to page 2-3 for more information about the readiness display.
	Attention. On the CHARGE-PAK—consult operating instructions. Refer to page 5-3 for more information about the CHARGE-PAK.
	Attention. On the safety warning—consult operating instructions. Refer to page 1-4 for more information about the warnings and cautions.
	Attention. On the electrode pads—consult operating instructions. Refer to page 2-6 for more information about electrode pads.
	Warning, high voltage.
	CHARGE-PAK Indicator. CHARGE-PAK needs to be replaced.
	Wrench Indicator. There is a condition that prevents or could prevent normal operation of the defibrillator. Refer to page 5-6 for more information.
	Power On/Off.
	Type BF patient connection.
	Symbol denoting a defibrillator and identifies the shock button.
LOT **YYWW**	Lot code.
REF	Reorder number.
	Do not reuse—single use only.
	Use By date shown: yyyy-mm-dd.

Symbol	Explanation
	See instructions for recycling procedure, page 5-6.
	See instructions for disposal procedure, page 5-4.
	Mark of conformity according to the European Medical Device Directive 93/42/EEC.
	Canadian Standards Association certification for Canada and the United States.
	For USA audiences only.
	Store in a cool, dry location (0° to 50°C or 32° to 122°F)
	Do not place near an open flame.
	Do not crush, puncture, or disassemble battery.
MIN	Manufacturer's Item Number
CAT	Catalog number used for placing orders

ABOUT THE LIFEPAK CR PLUS DEFIBRILLATOR

The LIFEPAK CR Plus Defibrillator is designed for indoor and outdoor use. There are two models available, fully automatic and semiautomatic. Once the electrode pads are applied, the fully automatic model monitors the patient and delivers a shock, if a shockable rhythm is detected, without any responder assistance. The semiautomatic model monitors the patient, but requires the responder to push the shock button, if a shockable rhythm is detected. The voice prompts of both models guide the responder through the process of using the defibrillator.

Capabilities and Features

The following paragraphs introduce specific features of both LIFEPAK CR Plus Defibrillator models.

Accessories

The LIFEPAK CR Plus Defibrillator arrives with a CHARGE-PAK installed, one preconnected electrode packet, a quick reference card, and operating instructions. Refer to Section 5 for other accessories.

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Automated Operation

Verbal prompts guide the responder through operation of the defibrillator.

The **fully automatic** LIFEPAK CR Plus Defibrillator requires no operator interaction beyond placing the electrode pads on the patient. If the defibrillator detects a shockable rhythm, it warns the responder prior to delivering any shock, then delivers a shock without operator interaction.

The **semiautomatic** LIFEPAK CR Plus Defibrillator has a highly visible shock button that the user presses when the defibrillator issues a shock instruction.

Automatic Self-Test

The LIFEPAK CR Plus Defibrillator tests itself each week and every time you turn it on. In addition, every month, the defibrillator performs a more extensive self-test. This self-test checks the defibrillator's circuitry to verify that it is ready for use.

Customized Setup

The LIFEPAK CR Plus Defibrillator is shipped ready to use with the preprogrammed ADAPTIV biphasic escalating energy protocol. The defibrillator also has several operating settings that can be customized. These include the defibrillator (name), voice prompt volume, energy sequence, and protocol.

Data Management

The LIFEPAK CR Plus Defibrillator digitally stores data when it is turned on and the electrode pads are applied to the patient. Patient data includes date and time, ECG data, and the number of shocks. The LIFEPAK CR Plus Defibrillator also stores the results of the automatic self-tests.

All patient and defibrillator data can be transferred to a PC by means of a serial infrared link, the IrDA port. A data transfer and management program running on the PC transfers event and test data from the defibrillator.

Defibrillation Electrodes (Pads)

QUIK-PAK™ defibrillation electrodes (pads) are applied to the patient so that the heart rhythm can be monitored and a shock delivered, if needed. If patient care is transferred to emergency medical personnel, these electrode pads can be disconnected from the LIFEPAK CR Plus Defibrillator and reconnected to other defibrillators equipped for QUIK-COMBO™ electrodes.

Defibrillation Waveform

The defibrillation shock, using ADAPTIV Biphasic technology, is delivered in the form of a biphasic truncated exponential (BTE) defibrillation waveform.

Heart Rhythm Analysis

The Medtronic patented Shock Advisory System™ evaluates the patient's heart rhythm.

Motion Detection

The patented motion system detects patient or operator motion that could affect the LIFEPAK CR Plus Defibrillator analysis of the heart rhythm. The heart rhythm evaluation is interrupted when the defibrillator detects motion.

Power System

Power is provided by a rechargeable internal lithium battery. A replaceable CHARGE-PAK functions as the charger for the internal battery. The internal battery supplies power to operate the defibrillator while the CHARGE-PAK provides a trickle charge for the internal battery. It is important to keep a fresh CHARGE-PAK in the defibrillator, even when the defibrillator is stored.

Readiness Display

This easy-to-read visual display indicates if the defibrillator is ready for use or if it needs attention.

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GETTING STARTED

This section provides an orientation to the LIFEPAK CR Plus Defibrillator and describes how to prepare it for use.

Unpacking and Inspecting the LIFEPAK CR Plus Defibrillator	page 2-2
Positioning the LIFEPAK CR Plus Defibrillator	2-2
Controls, Indicators, and Labels	2-3

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UNPACKING AND INSPECTING THE LIFEPAK CR PLUS DEFIBRILLATOR

Carefully remove the LIFEPAK CR Plus Defibrillator and the operating instructions from the box. To help ensure the integrity of your LIFEPAK CR Plus Defibrillator and to verify that it is complete, perform the initial inspection as follows:

1 Carefully examine the outside of the defibrillator for signs of damage that may have occurred during shipping.

2 Verify that a CHARGE-PAK is installed in the defibrillator. (See Figure 2-1.)

3 Verify that the OK symbol is visible in the readiness display.

4 Press the LID RELEASE/ON-OFF button. (This button opens the lid and turns on the defibrillator.)

- Verify that the QUIK-PAK™ defibrillation electrode pads are installed.
- Verify that the Use By date on the electrode packet has not passed.
- Verify that the voice prompt process begins.

5 Press and hold the LID RELEASE/ON-OFF button for approximately 2 seconds to turn off the defibrillator.

6 Close and latch the lid.

If any components are missing or the defibrillator appears to be damaged or the OK symbol is not visible, contact your dealer or Medtronic representative right away.

CAUTION!

After completing an initial inspection, do not open the lid unnecessarily. Each time you open the lid, the defibrillator turns on and internal battery power is reduced. After 30 minutes of cumulative on time, the CHARGE-PAK indicator will appear on the readiness display and the CHARGE-PAK and electrode packet will need to be replaced.

Save the shipping container and inserts in case you need to reship the defibrillator in the future.

POSITIONING THE LIFEPAK CR PLUS DEFIBRILLATOR

Position the LIFEPAK CR Plus Defibrillator in an easily accessible, unobstructed location. This could include a location near existing emergency equipment, such as fire extinguishers and first-aid kits. When considering location, avoid areas that expose the defibrillator to moisture, dust or extreme temperatures. The device and electrodes are designed to withstand environmental temperature fluctuations between -40°C (-40°F) to 50°C (122°F). Continuous exposure to temperatures above 23°C (73°F) will reduce the shelf life of the electrodes. Refer to Appendix A, page A-3 environmental specifications information.

You can position the defibrillator on a stable surface, or you can mount it using the wall mount bracket accessory. Refer to Supplies, Accessories, and Training Tools, page 5-7, for more information.

CONTROLS, INDICATORS, AND LABELS

This section introduces you to the controls, indicators, and labels on the LIFEPAK CR Plus Defibrillator.

Outside Controls, Indicators, and Labels

There are several important controls, indicators, and labels on the outside of the LIFEPAK CR Plus Defibrillator for you to become familiar with. They are identified in Figure 2-1 and described in Table 2-1.

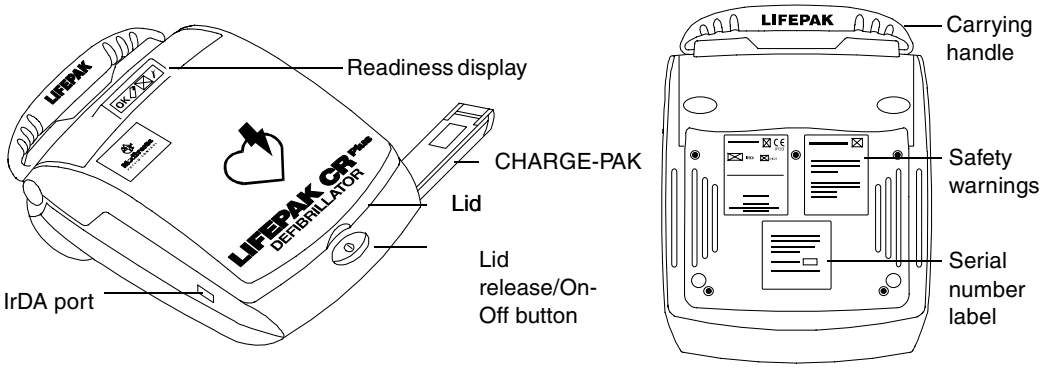

Figure 2-1 Outside Controls, Indicators, and Labels on the LIFEPAK CR Plus Defibrillator

Table 2-1 Outside Controls, Indicators, and Labels

Feature	Description
Readiness Display	Four indicators, visible when the defibrillator is turned off, allow you to determine, just by looking at the defibrillator, whether it's ready for use or needs attention. They include the following:
	OK The OK indicator is visible when the defibrillator is turned off and ready for use.
	The CHARGE-PAK indicator is visible when the CHARGE-PAK needs to be replaced or is not installed in the defibrillator. If needed, the defibrillator can be used in an emergency.
	The attention indicator appears when the internal battery is not fully charged. When this indicator first appears, the internal battery can power the defibrillator for a minimum of 6 shocks or 42 minutes.
	The wrench indicator appears when there is a condition that prevents or could prevent normal operation of the defibrillator.
Lid	The top of the LIFEPAK CR Plus Defibrillator.
LID RELEASE/ON-OFF button	The LID RELEASE/ON-OFF button opens the LIFEPAK CR Plus Defibrillator lid and turns the defibrillator on. Pressing and holding the button for approximately 2 seconds after the lid is open turns off the defibrillator.
CHARGE-PAK	The CHARGE-PAK functions as a battery charger, delivering a trickle charge to the internal battery. A CHARGE-PAK can provide a charge for approximately two years, as long as the defibrillator is not used.

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Table 2-1 Outside Controls, Indicators, and Labels (Continued)

Feature	Description
IrDA port	Infrared Data Association. This port provides wireless communications for transferring data from the defibrillator to a PC.
Carrying Handle	The carrying handle is used to transport the LIFEPAK CR Plus Defibrillator.
Safety Warnings	These warnings provide important information concerning the defibrillator's use and service.
Serial Number Label	This label includes the defibrillator identification number.

Inside Features

The inside features are designed to make the defibrillator easy to use during a cardiac arrest event. When you press the LID RELEASE/ON-OFF button, the lid opens, the defibrillator turns on, and you see the electrode packet and the release handle as shown in Figure 2-2. Table 2-2 describes all of the inside features.

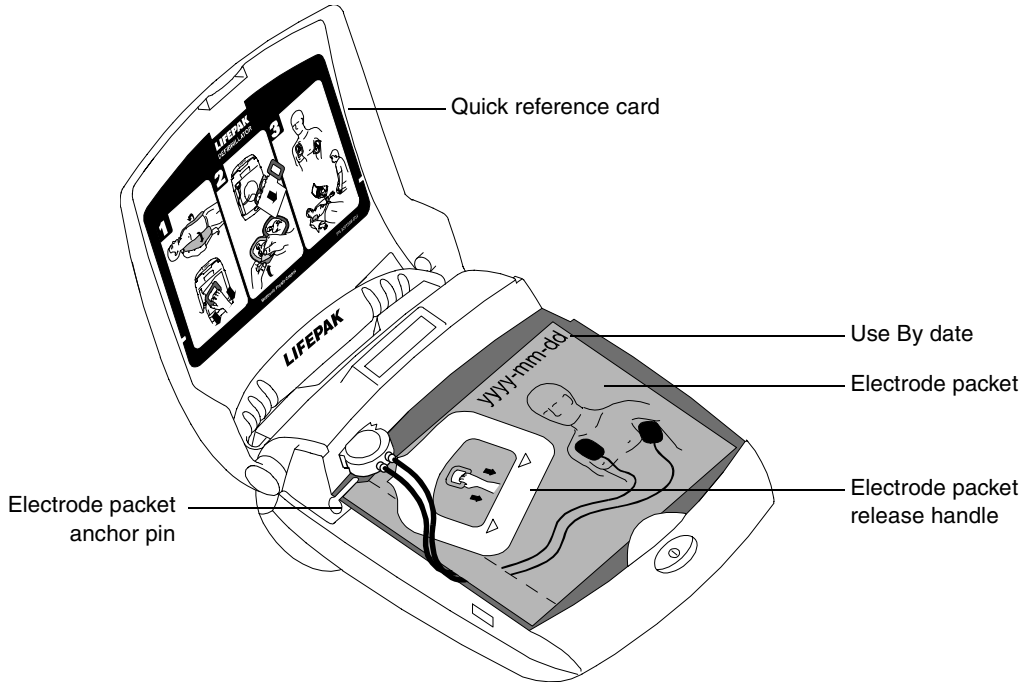

Figure 2-2 Inside Features of the LIFEPAK CR Plus Defibrillator

After you pull the electrode packet release handle and tear open the electrode packet, you will see the features shown in Figure 2-3.

Note: The SHOCK button is present only on the semiautomatic model.

The electrode pads are preconnected to the defibrillator. The electrode indicators will flash red until you apply the electrode pads to a patient's exposed chest. After they are applied to the patient, the indicators stop flashing and turn green.

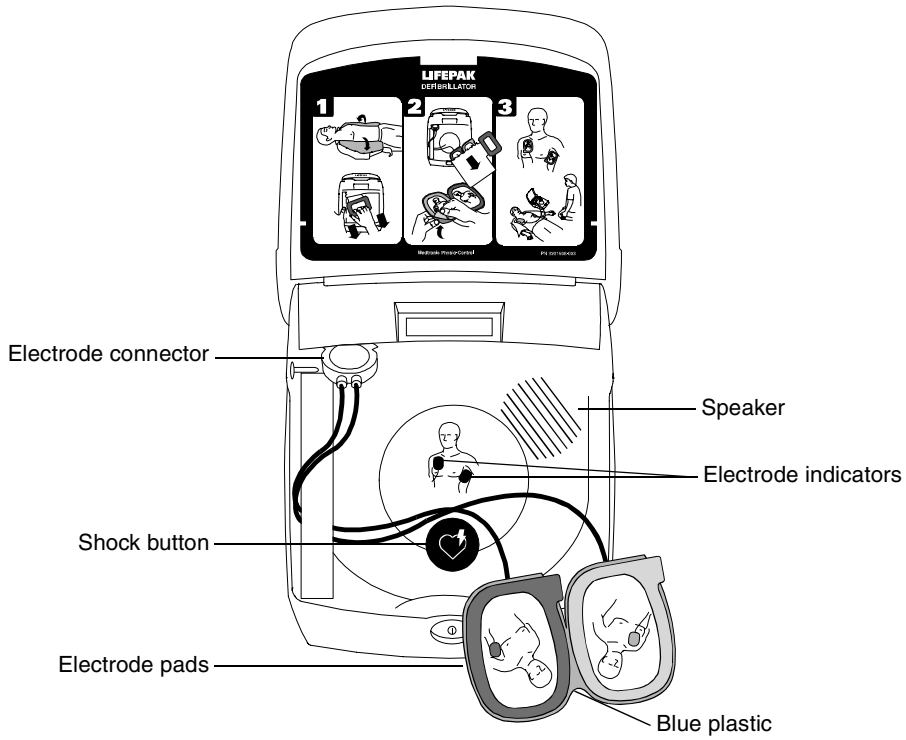

Figure 2-3 Inside Features after Opening the Electrode Packet

Table 2-2 Inside Features

Feature	Description
Blue plastic	The plastic liner that protects the conductive adhesive gel until the electrode pads are used.
Electrode connector	This connects the electrode pads to the defibrillator. To aid in patient transport, the connector can be unplugged from the LIFEPAK CR Plus Defibrillator and plugged into another defibrillator equipped for QUIK-COMBO electrodes.
Electrode indicators	The electrode indicators flash red until the electrode pads are applied to the patient's exposed chest. When the electrode pads are applied, the indicators turn solid green and the LIFEPAK CR Plus Defibrillator can perform an analysis. In addition, electrode indicators briefly flash when the defibrillator performs an automatic self-test.
Electrode packet	A set of electrode pads is stored in this packet.
Electrode packet anchor pin	This pin securely positions the electrode packet to the LIFEPAK CR Plus Defibrillator.
Electrode packet release handle	When you pull this handle, it tears open the electrode packet.

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Table 2-2 Inside Features (Continued)

Feature	Description
Electrode pads	The electrode pads are applied to the patient's exposed chest; they transfer the defibrillation energy (shock) to the patient. The electrode pads must be removed from the blue plastic before applying them to the patient.
Quick reference card	Step by step directions for using the LIFEPAK CR Plus Defibrillator to treat a patient in cardiac arrest.
Shock button	The SHOCK button is available only on the semiautomatic LIFEPAK CR Plus Defibrillator. Pressing this button will deliver a shock to the patient. You cannot deliver a shock to a patient unless the defibrillator instructs you to do so.
Speaker	This projects the voice prompts that lead you through the process of using the defibrillator.
Use By date	Use by date shown: yyyy-mm-dd. This date can be viewed through the clear plastic lid when it is closed.

USING THE LIFEPAK CR PLUS DEFIBRILLATOR

This section provides information and instructions for using the LIFEPAK CR Plus Defibrillator on a patient in cardiac arrest.

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WARNINGS AND CAUTIONS

To help ensure safe use of the LIFEPAK CR Plus Defibrillator, completely familiarize yourself with the following warnings and cautions.

WARNINGS!

Shock hazard.

When instructed "Do not touch patient," "Stand by," or "Everyone clear," remain still, do not touch the defibrillator, patient, electrode pads or any material in contact with the patient. Make sure no one is touching the patient when the defibrillator shocks the patient.

Shock hazard.

To remove an unwanted charge, disconnect the electrode cable from the defibrillator, wait for the defibrillator to automatically remove the charge, or turn off the defibrillator.

Possible fire, burns, and ineffective energy delivery.

During defibrillation, material in contact with the electrode pads can cause electrical sparks, skin burns, and divert important defibrillating energy away from the heart. Place electrode pads so that they adhere to the skin completely. Do not allow the electrode pads to touch each other, medication patches, dressings or any other material on the patient's chest.

CAUTION!

Possible equipment damage.

Before using the defibrillator, disconnect all equipment from the patient that is not defibrillator-protected.

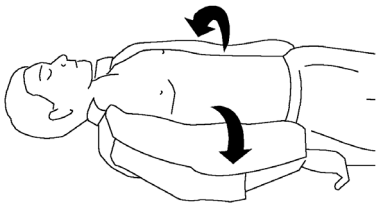
RESPONDING TO A CARDIAC ARREST PATIENT

If not treated, cardiac arrest will cause death. In a cardiac arrest situation, it is important to remember to immediately call for help and activate your emergency response system.

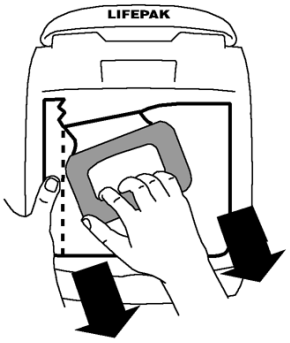
Basic Steps for Using the LIFEPAK CR Plus Defibrillator

Responding to a cardiac arrest patient using the LIFEPAK CR Plus Defibrillator involves these basic steps:

Establish that the patient is in cardiac arrest, as instructed in your CPR training. Place the LIFEPAK CR Plus Defibrillator near the patient and press the LID RELEASE/ON-OFF button to open the lid and turn on the defibrillator. The voice prompt sequence begins, guiding you through the response steps.

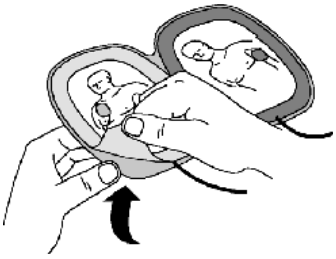


Expose the patient's chest. If the patient's chest is excessively hairy, shave the hair. If the patient's chest is dirty or wet, wipe the chest clean and dry.

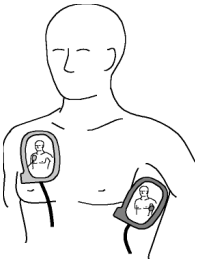


Hold down the left side of the electrode packet with one hand and pull the red electrode packet handle down with the other. The electrode packet will tear open.

Completely open the packet and remove the electrode pads. A small piece of the packet will remain attached to the defibrillator.



Remove the electrode pads, one at a time, from the blue plastic.



Apply the electrode pads to the patient's exposed chest, as shown.

Listen to the voice prompts and do not touch the patient unless instructed to do so.

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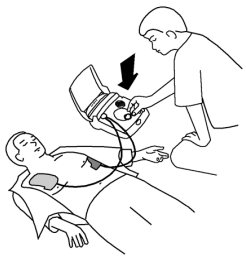
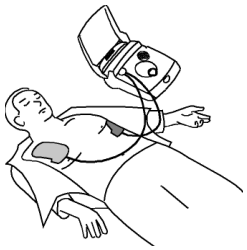


Always check to be sure that no one is touching the patient and that nothing is in contact with the patient before pressing the SHOCK button when instructed (semiautomatic model), or whenever the defibrillator indicates it is preparing to deliver a shock (automatic model).



If the patient starts moving or breathing, keep the electrode pads on the patient and connected to the defibrillator. Place the patient in the recovery position, if possible, as instructed in your training.

What to Do After Emergency Medical Personnel Arrive

When emergency medical personnel arrive, tell them what actions you have taken. Tell them how long the patient has been unconscious, if you delivered shocks, the number of shocks delivered, and if you performed CPR.

Do not worry if you cannot recall precisely what happened. The defibrillator makes a digital recording of heart rhythms and shocks that can be transferred to a computer at a later time. Refer to Section 4 for information on transferring patient data.

Without removing the electrode pads from the patient, emergency medical personnel can disconnect the electrode pads from the LIFEPAK CR Plus Defibrillator and reconnect them to another defibrillator that has a compatible QUIK-COMBO cable.

To disconnect the electrode pads:

1 Pull the electrode cable straight out from the defibrillator.

2 Remove the electrode packet anchor pin from the slot in the defibrillator.

3 Press the LID RELEASE/ON-OFF button and close the lid to turn off the LIFEPAK CR Plus Defibrillator.

What to Do After Using the LIFEPAK CR Plus Defibrillator

After you use the LIFEPAK CR Plus Defibrillator to respond to a patient in cardiac arrest, complete the following tasks:

1 If the defibrillator is turned on, press and hold the LID RELEASE/ON-OFF button for approximately 2 seconds to turn it off.

2 Clean the LIFEPAK CR Plus Defibrillator and its accessories, according to the instructions provided in Table 5-1, page 5-2. Use only the cleaning agents identified in Table 5-1.

3 Transfer data, if desired.

4 Replace the CHARGE-PAK. (Refer to page 5-3.)

5 Install a new electrode packet. (Refer to page 5-4.)

6 Close the lid and verify that the OK symbol appears in the readiness display, indicating that the defibrillator is ready for use. If the attention symbol ⚠ appears after you replace the CHARGE-PAK, the internal battery needs additional time to reach an adequate charge capacity. (Refer to page 5-4 for charge times.)

7 Dispose of the used electrode pads, any unused, spare electrode pads, and the CHARGE-PAK. (Refer to Recycling Information, page 5-6.)

VOICE PROMPTS AND TONES

The LIFEPAK CR Plus Defibrillator voice prompts provide clear, step-by-step instructions for responding to a patient in cardiac arrest. In addition, the defibrillator may emit sounds that alert you to the actions that the defibrillator is performing.

Note: A few seconds may pass between voice prompts and tones. Always wait for further instructions before taking action.

Note: Some voice prompts will repeat throughout the event.

Table 3-1 lists each of the voice prompts and tones (if any), specifies what to do, and identifies defibrillator performance variations.

Table 3-1 Voice Prompts, Tones, and User Responses

Voice Prompt/Tone	What To Do	Defibrillator Performance Variations
CALL FOR HELP NOW	If you haven't already called your area's emergency medical system, do so now.	If the *CALL FOR HELP* prompt is not enabled, you will hear three consecutive beeps after opening the lid.
REMOVE CLOTHING FROM CHEST	Remove all clothing from the patient's chest (both male and female). If necessary, prepare the patient's chest as described on page 3-2.	
PULL RED HANDLE TO OPEN BAG	Hold down the left side of the electrode packet and pull down the red electrode packet release handle. Tear the electrode packet completely open, exposing the electrode pads.	
PEEL EACH PAD OFF BLUE PLASTIC	Peel one electrode pad away from the blue plastic and apply it to the patient's chest. Repeat this process with the other pad.	
AND APPLY PADS TO EXPOSED CHEST	Firmly apply each electrode pad to the patient's exposed chest in the location indicated by the picture on the electrode pad.	

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Table 3-1 Voice Prompts, Tones, and User Responses (Continued)

Voice Prompt/Tone	What To Do	Defibrillator Performance Variations
DO NOT TOUCH PATIENT *EVALUATING HEART RHYTHM*	Do not touch the patient, the electrode pads, wires, or the defibrillator.	If the defibrillator detects movement while it is evaluating the heart rhythm, you will hear *MOTION DETECTED—STOP MOTION*.
STAND BY *PREPARING TO SHOCK*	Do not touch the patient. The defibrillator has detected a shockable rhythm.	
CHARGING	Do not touch the patient.	
EVERYONE CLEAR	Make sure that you and any bystanders do not touch the patient, the electrodes, the defibrillator, or anything in contact with the patient.	The semiautomatic model will follow this message with *PRESS FLASHING BUTTON* prompt.
PRESS FLASHING BUTTON plus a tone	Do not touch the patient. Make sure that no one else is touching the patient. Press the red flashing shock button to deliver energy to the patient.	The fully automatic model does not include this prompt. If a shockable rhythm is detected, it will automatically deliver a shock after issuing the *DELIVERING SHOCK* prompt and tone.
DO NOT TOUCH PATIENT *DELIVERING SHOCK* plus a tone	Do not touch the patient. The defibrillator is about to deliver a shock.	The semiautomatic model does not include this prompt. If a shockable rhythm is detected, the semiautomatic model will prompt you to press the flashing button.
SHOCK DELIVERED	Do not touch the patient. Wait for further voice prompts.	
SHOCK NOT DELIVERED	You hear this prompt if, after a shock instruction is given, no shock was delivered within 15 seconds. The defibrillator will again evaluate the heart rhythm. Continue listening to the defibrillator for instructions.	
NO SHOCK ADVISED	The defibrillator detected a nonshockable rhythm. Wait for the next instruction.	This indicates no detectable electrical activity in the heart.
CHECK FOR PULSE	Feel the patient's neck for up to 10 seconds to check for a pulse. Check the patient for breathing. Check the patient for signs of circulation.	*CHECK FOR BREATHING* *CHECK FOR SIGNS OF CIRCULATION*
IF NO PULSE, START CPR	If you do not feel a pulse or the patient is not breathing, or you do not see signs of circulation, give two breaths and 15 chest compressions. Repeat until instructed to stand clear.	*IF NOT BREATHING, START CPR* *IF NO SIGNS OF CIRCULATION, START CPR*

Table 3-1 Voice Prompts, Tones, and User Responses (Continued)

Voice Prompt/Tone	What To Do	Defibrillator Performance Variations
CONTINUE CARE	Continue the activity you are doing at the time the prompt occurs.	
CHECK PADS FOR GOOD CONTACT	Check electrode pads for good contact on patient's chest. Firmly press the electrode pads onto the patient's chest. (Also refer to Troubleshooting During Patient Use.)	
MOTION DETECTED	Check to see if the patient is moving or breathing normally. Check to see if someone is touching the patient or the defibrillator. (Also refer to Troubleshooting During Patient Use.)	
STOP MOTION	Do not touch the patient. (Also refer to Troubleshooting During Patient Use).	
CALL SERVICE	Contact authorized service personnel.	

TROUBLESHOOTING DURING PATIENT USE

Under normal conditions the LIFEPAK CR Plus Defibrillator will operate successfully. This section explains problem conditions that you may encounter while using the LIFEPAK CR Plus Defibrillator. For information about keeping your defibrillator in a state of readiness, refer to Section 5.

Table 3-2 Troubleshooting During Patient Use

Problem	Possible Cause	What To Do
CHECK PADS FOR GOOD CONTACT voice prompt is heard	Inadequate connection to the defibrillator	• Be sure that the connector is completely inserted.
	Electrode pads are not adhered properly to the patient	• Firmly press electrodes on patient's skin. • Clean, shave, and dry the patient's skin prior to placing pads on skin.
	Electrode pads are dry, damaged, or have passed the expiration date	• Replace the electrode pads.
	Electrode pads are not removed from the blue plastic	• Remove the electrode pads from the blue plastic and apply them to the patient's chest.

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Table 3-2 Troubleshooting During Patient Use (Continued)

Problem	Possible Cause	What To Do
Defibrillator cannot deliver the required shock	Defibrillator internal battery power is low	• Administer CPR if the patient is not responding, not breathing normally, not moving, or if you cannot detect a pulse.
Voice prompts sound faint or distorted	Defibrillator internal battery power is low	• Administer CPR if the patient is not responding, not breathing normally, not moving, or if you cannot detect a pulse.
MOTION DETECTED and *STOP MOTION* voice prompts are heard	Patient movement because of location	• Move patient to stable location, if possible.
	Patient movement because of breathing	• Stop CPR during analysis. • Check patient for normal breathing.
	Vehicle motion	• Stop vehicle during analysis, if possible.
	Electrical/radio frequency interference	• Move communication or other suspected devices away from the defibrillator when possible.
Defibrillator does not deliver voice prompts or beeping tones after you open it (turn it on)	Depleted internal battery	• Administer CPR if the patient is not responding, not breathing normally, not moving, or if you cannot detect a pulse. • Replace the CHARGE-PAK as soon as possible. After the OK symbol appears on the readiness display, return the defibrillator to service. • Contact authorized service personnel.
The readiness display is blank	The defibrillator has been turned on	• Normal condition when the defibrillator is in use.
	Operating temperature is too low or too high	• Operate the defibrillator within 0° to 50°C (32° to 122°F).
	LCD not operating properly	• Contact authorized service personnel.

DATA STORAGE

This section describes the data that the LIFEPAK CR Plus Defibrillator stores during patient use.

This manual does not provide instructions for how to hand off patient data to your emergency medical system or hospital personnel. Because this process varies from area to area, check with your emergency medical system administration for information and directions.

Overview of Data Storage page 4-2

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OVERVIEW OF DATA STORAGE

Each time you use the LIFEPAK CR Plus Defibrillator, it digitally saves patient data that can be transferred to a PC. Patient data can be provided to emergency medical personnel or hospital personnel to aid in case review for quality control, training, and research purposes. We recommend that you become familiar with their local requirements for reporting a use of the LIFEPAK CR Plus Defibrillator and for providing use data. For assistance in retrieving data from the defibrillator, contact your local Medtronic sales or service representative.

Data Stored by the LIFEPAK CR Plus Defibrillator

Whenever you turn on the LIFEPAK CR Plus Defibrillator and connect it to a patient, it automatically stores data about the patient. When this data is transferred to a data management system (for example, CODE-STAT™ Suite) for review, three patient reports are available: an Event Log, Continuous ECG, and a Summary. Table 4-1 describes these reports.

Table 4-1 Patient Reports

Report Type	Description
Event Log	A chronological log of all events. An event is a condition noted by the defibrillator. Events are listed on page 4-3.
Continuous ECG	Twenty minutes of the patient's ECG rhythm beginning when the patient is connected to the defibrillator and ending when the defibrillator is turned off.
Summary	Combines the Event Log and a sampling of continuous ECG rhythms associated with certain events.

The LIFEPAK CR Plus Defibrillator can store up to two patient use records: one for the current patient and one for the previous patient. When you use the LIFEPAK CR Plus Defibrillator, it is important that you transfer the patient data as soon as possible after use to free up storage.

The Complete Record for the current patient includes the Continuous ECG and Event Log. If you treat a second patient, the first patient's Complete Record will be reformatted into a Summary report. If you treat a third patient, all of the first patient's data will be deleted and the second patient's Complete Record will be reformatted into a Summary Report. Refer to Table 4-2.

Table 4-2 LIFEPAK CR Plus Defibrillator Patient Records

	Complete Record	Summary
Current Patient	X	X
Previous Patient	ø	X

If you turn the defibrillator on and off without attaching electrode pads to a patient, the defibrillator will not create a new patient record and the patient records in the defibrillator will not be altered.

The LIFEPAK CR Plus Defibrillator does not delete patient data after you transfer the data to a PC. The defibrillator only deletes previous patient data when it is connected to a new patient.

Test and Service Data

The LIFEPAK CR Plus Defibrillator stores a test log consisting of the most recent auto-tests, power cycles, and CHARGE-PAK replacements. The test log lists the test results and any errors detected. The test log data is available only to service personnel or to users through the CODE-STAT™ Suite data management system.

Event and Test Log

Table 4-3 lists the types of events (and their associated voice prompts) that may be annotated on event and test log reports.

Table 4-3 Event and Test Log Reports

Event	Voice Prompt
Event Log:	
Power On	None
Connect Electrodes	Check pads for good contact
Patient Connected	None
Initial Rhythm*	None
Analysis X*	Evaluating heart rhythm
Shock Advised	Standby, preparing to shock
Charge Complete	Everyone clear, press flashing button; or Everyone clear, do not touch patient, delivering shock
SHOCK X-XXXJ*	Shock delivered
Shock X Abnormal	None
No Shock Advised	No shock advised
CPR Prompt	Start CPR
Stop CPR Prompt	Do not touch patient
Check Patient*	Do not touch patient
Charge Removed	Shock not delivered
Low Battery	None
Motion	Motion detected, stop motion
Analysis Stopped*	None
Out of Event Memory	None
Out of Waveform Memory	None
Power Off	None
Test Log:	
Self Test Power On	
Self Test Pass/Fail	
User Power On	
CHARGE-PAK Changed	
CHARGE-PAK	
Fault Log	

*These events include ECG samples in the Summary Report.

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CARING FOR THE LIFEPAK CR PLUS DEFIBRILLATOR

This section explains how to help keep your LIFEPAK CR Plus Defibrillator in good working condition. Cared for properly, your LIFEPAK CR Plus Defibrillator is built to give you many years of service.

Maintaining a State of Readiness	page 5-2
Cleaning the LIFEPAK CR Plus Defibrillator	5-2
Replacing the CHARGE-PAK Battery Charger and the QUIK-PAK Electrode Packet	5-3
Obtaining Authorized Service	5-6
Recycling Information	5-6
Supplies, Accessories, and Training Tools	5-7
Warranty Information	5-7

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MAINTAINING A STATE OF READINESS

The LIFEPAK CR Plus Defibrillator does not require routine maintenance. The defibrillator performs an automatic self-test once a week and every time you turn it on. The electrode indicators briefly flash during the test. If the automatic self-test detects a condition that requires attention, the OK symbol in the readiness display will fade and either the CHARGE-PAK symbol, the ATTENTION symbol, or the WRENCH symbol will appear, depending on the type of condition detected.

On a regular basis, you should do the following:

- Check to make sure that the OK symbol is visible in the readiness display.
- Check the Use By date on the electrode packet (visible through the clear plastic lid in the upper right-hand corner). If the date has passed, replace the electrode packet and the CHARGE-PAK in the defibrillator.
- Check other emergency supplies that may be stored with the defibrillator.

When establishing your local inspection schedule, consider how often the defibrillator will be used and how familiar the operators are with using a defibrillator. For example, if the defibrillator is used only rarely, monthly inspections may be appropriate. An inspection checklist is provided in Appendix D.

CLEANING THE LIFEPAK CR PLUS DEFIBRILLATOR

CAUTION!

Possible equipment damage.

Do not clean any part of the defibrillator or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the defibrillator or its accessories.

Table 5-1 Cleaning Methods

Item	Cleaning Method	Cleaning Agent
LIFEPAK CR Plus Defibrillator exterior case, readiness display, and crevices	Clean with damp sponge or cloth.	Nonabrasive soap and water. Quaternary ammonium compounds. Rubbing (isopropyl) alcohol. Peroxide (peracetic acid) solutions.
CHARGE-PAK	None.	None. Dispose of/recycle after use.
Electrode Pads	None. Do not remove electrode pads from the packet.	None. Dispose of/recycle after use.
Carrying case	Wipe with damp cloth or sponge.	Water.
Quick Reference Guide	Wipe with damp cloth or sponge.	Water.

REPLACING THE CHARGE-PAK BATTERY CHARGER AND THE QUIK-PAK ELECTRODE PACKET

Use the Medtronic replacement kit to replace the CHARGE-PAK and the QUIK-PAK electrode packet as follows:

- After each use of the defibrillator
- If the CHARGE-PAK indicator appears on the readiness display

When installed, these two accessories will allow the defibrillator to stand by for patient use for approximately 2 years. The electrode packet Use By date is programmed into the CHARGE-PAK. When the date is reached, the CHARGE-PAK indicator will appear on the readiness display, indicating the CHARGE-PAK and electrode packet need to be replaced.

Replacing the CHARGE-PAK

The CHARGE-PAK is a replaceable, non-rechargeable battery cell that provides a trickle charge to the internal battery. The internal battery provides the power for the LIFEPAK CR Plus Defibrillator. To prevent damage to the internal battery, always keep a functional CHARGE-PAK in the defibrillator, including during storage or shipping.

Replace the CHARGE-PAK when the CHARGE-PAK indicator appears in the readiness display and after each use of the defibrillator. Replace the CHARGE-PAK and the QUIK-PAK at the same time. To replace a CHARGE-PAK:

1 Remove the used CHARGE-PAK by pressing the release latch. The CHARGE-PAK will spring outward from the defibrillator. (See Figure 5-1 for CHARGE-PAK location.)

2 Slide the used CHARGE-PAK out of the defibrillator.

3 Insert the new CHARGE-PAK into the defibrillator as shown in Figure 5-1.

4 Push the new CHARGE-PAK into the defibrillator until you hear it click into position. If the CHARGE-PAK is not completely inserted, it will spring back out.

5 Confirm that the CHARGE-PAK indicator disappears and that the OK symbol appears in the readiness display.

6 Dispose of the used CHARGE-PAK properly. Do not place in the trash. (Refer to page 5-4 for more information about disposal).

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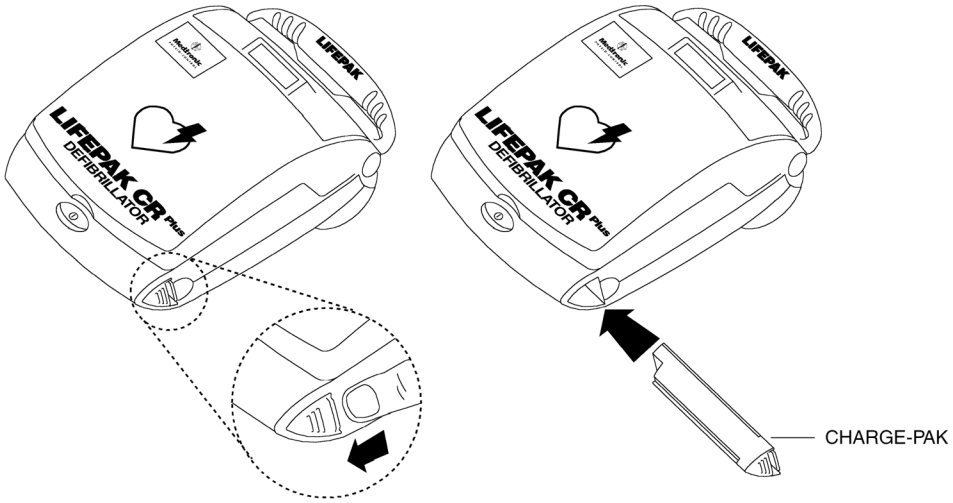

Figure 5-1 Removing and Replacing the CHARGE-PAK

If the attention symbol ⚠ appears after you have replaced the CHARGE-PAK, the internal battery needs additional time to reach an adequate charge capacity. The time it will take for the internal battery to reach capacity at temperatures above 15°C (59°F) is as follows:

Capacity	Charge Time
6 shocks, 42 minutes “On time”	48 hours
20 shocks, 140 minutes “On time”	14 days

CAUTION!

Possible equipment damage.

Keep the defibrillator at temperatures above 0°C (32°F) and below 50°C (122°F) for optimum internal battery charging. The battery may not charge effectively at lower temperatures and temperatures in excess of 50°C (122°F) for longer than one week can result in permanent damage to the internal battery.

CHARGE-PAK Disposal

The CHARGE-PAK battery charger is made of cells composed of lithium sulfuryl chloride chemistry. It has the same chemical constituents as lithium thionyl chloride batteries but in different ratios. Dispose of the CHARGE-PAK according to local, state, and federal regulations, which vary from country to country. In most countries, placing used battery cells in the trash is prohibited. These cells should not be incinerated, unless suitable procedures are followed and appropriate precautions are taken by qualified handlers. Exposing these cells to high temperatures or fire can cause the cells to vent and/or rupture.

CHARGE-PAK disposal can be accomplished through non-profit organizations mandated by local authorities or organized by professionals. Waste management companies may also assist in the disposal of these battery cells. If local disposal services are not available, it is recommended that used CHARGE-PAKs be shipped to the recycling firm ToxCo using the instructions and packing materials supplied with the CHARGE-PAK and QUIK-PAK replacement kit. You can contact ToxCo as follows: ToxCo Inc., 3200 E. Frontera, Anaheim, CA USA, 92806; (714) 879.2067; www.Toxco.com.

Replacing the QUIK-PAK

Use a new set of QUIK-PAK electrode pads on each patient. Replace the QUIK-PAK after each use or when the Use By date is passed. Replace the QUIK-PAK and CHARGE-PAK at the same time because the Use By date is the same for both. Discard used electrode pads and any unused, spare electrode pads according to recycling instructions on page 5-6. To replace the QUIK-PAK:

1 Open the lid (voice prompts will begin).

2 Press and hold the LID RELEASE/ON-OFF button for approximately 2 seconds to turn off the defibrillator.

3 Unplug the electrode connector.

4 Remove the electrode packet anchor pin from the slot in the defibrillator.

5 Inspect the new electrode packet and confirm that the Use By date has not passed.

6 Slide the electrode anchor pin into the slot on the defibrillator.

7 Plug in the new electrode connector.

8 Ensure that the new electrode packet is centered on the defibrillator and tucked behind the lip before closing the lid.

9 Close the lid and confirm that the packet Use By date is visible in the upper right-hand corner.

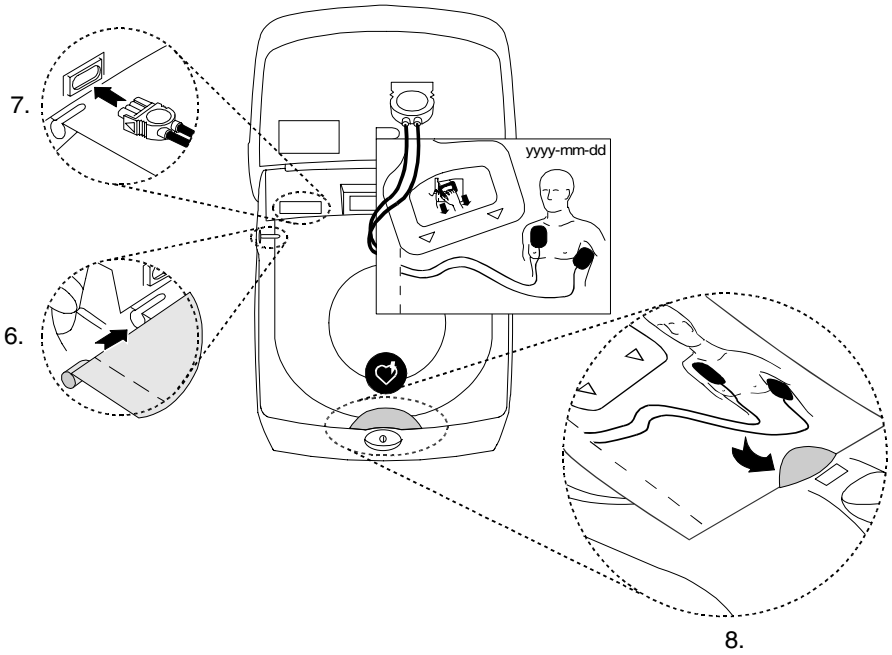

Figure 5-2 Replacing Electrode Packet

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OBTAINING AUTHORIZED SERVICE

WARNING!

Shock hazard.

Do not disassemble the defibrillator. It contains no operator-serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

The WRENCH indicator appears on the readiness display if the LIFEPAK CR Plus Defibrillator requires service. Contact authorized service personnel only. In the USA, contact Medtronic Technical Support at 1.800.442.1142. Outside the USA, contact your local Medtronic representative. Be prepared to provide the following information:

- Model number and part number
- Serial number
- Description of the problem based on your observations
- If the defibrillator needs to be shipped to a service center or to the factory, pack the defibrillator in the original shipping container. If this is not possible, ship the defibrillator in protective packing to prevent shipping damage.

RECYCLING INFORMATION

Recycle the defibrillator and its accessories at the end of their useful life.

Recycling Assistance

Items should be recycled according to national and local regulations. Contact your local Medtronic representative for assistance.

Preparation

Items should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes

After using disposable electrodes, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

SUPPLIES, ACCESSORIES, AND TRAINING TOOLS

Table 5-2 lists supplies, accessories, and training tools for the LIFEPAK CR Plus Defibrillator. To order in the USA, call 1.800.442.1142. Outside the USA, contact your local Medtronic representative.

Table 5-2 Supplies, Accessories, and Training Tools

Item Description	Part Number
Replacement kit (CHARGE-PAK battery charger and QUIK-PAK electrode packet)	3201616
Infant/Child Reduced Energy Defibrillation Electrodes (not compatible with the QUIK-COMBO defibrillation cable, monophasic LIFEPAK 500 or unmodified biphasic LIFEPAK 500 AEDs)	3202380
External carrying case	3201582
Ambu™ First Responder Kit	3011042
Wall mount bracket	3201124
LIFEPAK CR–T AED Trainer	3201617
Quick Reference Card	3201619
Operating Instructions	3201686
LIFEPAK CR Plus Orientation Video	3201620
IrDA Adapter (attachment for a PC)	3202608
CODE-STAT Suite data management system	CSS order
LIFENET® DT Express information management system	3202165

WARRANTY INFORMATION

Refer to the product warranty statement included with your LIFEPAK CR Plus Defibrillator. For duplicate copies, contact your local Medtronic representative.

!USA

As provided under the Product Warranty Statement: New and demo LIFEPAK CR Plus automated external defibrillators and internal battery systems, used exclusively in commercial and consumer settings, are under limited warranty for 5 years. New and demo LIFEPAK CR Plus automated external defibrillators and internal battery systems used in out-of-hospital, professional emergency medical and mobile applications, are under limited warranty for 1 year. The CHARGE-PAK battery charger is under limited warranty for 90 days.

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LIFEPAK CR PLUS DEFIBRILLATOR OPERATING SETTINGS

This section introduces the operating settings that you may adjust on the LIFEPAK CR Plus Defibrillator.

Operating Settings and Setup Configuration page 6-2

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OPERATING SETTINGS AND SETUP CONFIGURATION

The LIFEPAK CR Plus Defibrillator has 12 operating settings that affect how the defibrillator functions. The settings range from defining the time and date used by the defibrillator, to the energy sequence and protocol of the shocks delivered. This group of operating settings are the defibrillator's setup configuration.

Each operating setting is preset to a default value based on clinical guidelines and does not need to be changed unless you desire performance characteristics that are different from the default setting.

Table 6-1 identifies operating settings in the setup configuration, describes each setting, including possible options, and identifies the preset defaults. For assistance in changing the settings in your LIFEPAK CR Plus, contact your local Medtronic sales or service representative.

Table 6-1 Operating Settings

Operating Settings	Description	Default Setting
Device ID	A unique identifier (ID) assigned to each LIFEPAK CR Plus Defibrillator for tracking the location of defibrillators. If you have multiple defibrillators at your location, you should give each a unique name, such as Building 1, Building 2, and so on. When you transfer event data from the defibrillator to a PC, the defibrillator ID will be included in the transferred data.	Serial Number
Energy Sequence	Energy sequence defines the energy levels used by the LIFEPAK CR Plus Defibrillator. The different energy levels for the USA are: Energy level 1 — 200 joules Energy level 2 — 200, 225, 250, 275, 300 joules Energy level 3 — 200, 225, 250, 275, 300, 325, 360 joules The different energy levels for outside the USA are: Energy level 1 — 150, 175, 200 joules Energy level 2 — 150, 175, 200, 225, 250, 275, 300 joules Energy level 3 — 150, 175, 200, 225, 250, 275, 300, 325, 360 joules	Level 1 – 200 Level 2 – 300 Level 3 – 360

Table 6-1 Operating Settings (Continued)

Operating Settings	Description	Default Setting
Energy Protocol	Energy protocol determines how the LIFEPAK CR Plus Defibrillator delivers successive shocks. There are two options for this setting: flexible or fixed. Flexible sequence means the energy delivered for a shock increases only if an analysis immediately following a shock results in another SHOCK ADVISED decision. For example, if the defibrillator energy sequence is set up as 200, 300, 360, flexible sequence means that the energy delivered for the first shock is 200 joules. If the arrhythmia is terminated by shock 1 and the next analysis results in a NO SHOCK ADVISED decision, the energy will not increase for the next shock. However, if the arrhythmia is not terminated by shock 1 and the next analysis results in a SHOCK ADVISED decision, the energy will increase to 300 joules, and so on. Fixed sequence means that the energy delivered after the first shock of 200 joules increases from 200 to 300, and then to 360 joules, regardless of the post-shock ECG rhythm and subsequent analysis.	Flexible
CPR Time 1 CPR Time 2	The CPR Time 1 and CPR Time 2 settings define the time interval that you perform CPR. CPR Time 1 is the time interval following three shocks. CPR Time 2 is the time interval following a NO SHOCK ADVISED decision. The choices for CPR Time 1 and CPR Time 2 are 15, 30, 45, 60, 90, 120, and 180 seconds.	CPR Time 1–60 sec CPR Time 2–60 sec
Device Date Device Time	This lets you set the current time and date.	Pacific Standard Time and Date
Turn-On Prompt	This setting lets you choose whether you hear only tones or tones and the voice prompt, CALL FOR HELP NOW, when you open the lid and the defibrillator turns on. Choices are Voice and Tones.	Voice
Voice Prompt Volume	This setting lets you set the voice prompt volume to MEDIUM or HIGH.	High
Pulse Prompt	This setting lets you choose whether the defibrillator prompts you to check the patient's pulse (appropriate for medically trained users) or to check patient for signs of circulation such as breathing and movement (appropriate for lay users). Choices are Check Pulse, Check Breathing, or Check Circulation.	Per customer order

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Table 6-1 Operating Settings (Continued)

Operating Settings	Description	Default Setting
Motion Detection	This setting determines whether motion detection is active during analysis. When motion detection is On, the defibrillator stops analysis if it detects any patient motion and then notifies the responder of the problem. The defibrillator will not resume analysis until the motion is no longer detected. When motion detection is Off, analysis will continue regardless of any patient motion.	On
Time Zone	This setting lets you set the time zone for the location of the defibrillator. Choices are 74 time zones with universal time code (UTC).	None

APPENDIX A
SPECIFICATIONS

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SPECIFICATIONS

All specifications are at 20°C (68°F) unless otherwise stated.

Defibrillator

Waveform:	Biphasic Truncated Exponential, with voltage and duration compensation for patient impedance. See Figure A-1.
Output Energy Sequence*:	Multiple levels, user configurable from 200 joules to 360 joules (150 joules min outside the USA).
Output Energy Accuracy*:	±10% into 50 ohms ±15% into 25 to 100 ohms

Patient Impedance (Ω)	Phase 1 Duration (ms)		Phase 2 Duration (ms)		Tilt (%)
	Min	Max	Min	Max	Nominal
25	5.1	6.0	3.4	4.0	77.5
50	6.8	7.9	4.5	5.3	65.8
100	8.7	10.6	5.8	7.1	52.6
125	9.5	11.2	6.3	7.4	47.8

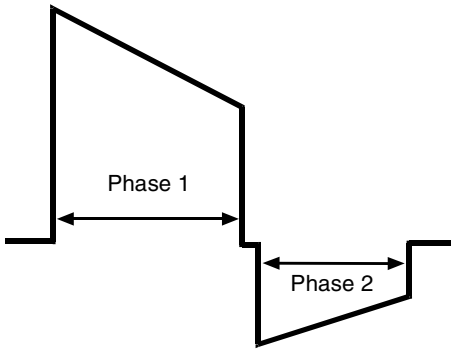

Figure A-1 Biphasic Waveform

Shock Advisory System:	An ECG analysis system that advises whether a shock is appropriate, meets rhythm recognition criteria specified in DF39. The device allows a defibrillation shock only if the Shock Advisory System advises defibrillation.
Device Capacity:	Thirty (30) full discharges or 210 minutes of “on time” with a fully charged device.

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Shock Charge Time:	Charge times with a fully charged device: 200 joules in less than 9 seconds 360 joules in less than 15 seconds Charge time after 15 discharges delivered from a fully charged device: 360 joules in less than 15 seconds
System Recharge Times:	Recharge times with a fully discharged device: Able to deliver 6 shocks or provide 42 minutes of operating time after 48 hours of recharge and 20 shocks or 140 minutes of operating time after 14 days of recharge time with a new CHARGE-PAK at temperatures above 15°C (59°F).
Controls:	LID RELEASE/ON-OFF button—Controls device power. SHOCK button (semiautomatic version)—Delivers defibrillation energy. After electrodes are attached to a patient, an automatic version of the device delivers a shock, if appropriate, not requiring operator intervention.
Electrical Protection:	Input protected against high voltage defibrillator pulses per IEC60601-1/EN60601-1. See Figure A-2.

Figure A-2 Defibrillation-protected, type BF patient connection

Safety Classification:	Internally powered equipment. IEC60601-1/EN60601-1.

* These specifications apply from 25 to 200 ohms. Voltage compensation is limited to the voltage that would result in delivery of 360 joules into 50 ohms.

User Interface

User Interface:	The user interface includes voice prompts, audible tones, graphical prompts, and operator actions.
Readiness Display	The readiness display shows the device status.

OK Indicator:	Indicates OK when the last self test was completed successfully. When the OK indicator is visible, all other indicators are not visible. The OK indicator is not displayed during device operation.
CHARGE-PAK Indicator:	When displayed, replace the CHARGE-PAK battery charger.

Attention Indicator:	When first displayed, at least 6 discharges or 42 minutes of operating time will remain.
Service Indicator:	Service required when displayed.

Environmental

Note: All performance specifications defined assume that the unit has been stored (two hours minimum) at the operating temperature prior to operation.

Operating Temperature:	0 to 50°C* (32 to 122°F)
Storage Temperature:	-40 to 70°C* (-40 to 158°F) with CHARGE-PAK and electrodes, maximum exposure time limited to one week.
Atmospheric Pressure:	760 mmHg to 429 mmHg, 0 to 15,000 feet above sea level.
Relative Humidity:	5 to 95% (non-condensing)
Water Resistance:	IEC60529/EN60529 IPX4 “Splash proof” with electrodes connected and CHARGE-PAK installed.
Shock:	Shock: MIL-STD-810E, Method 516.4, Procedure 1, (40g, 6 to 9 msec pulse, ½ sine each axis).
Vibration:	MIL-STD-810E, Method 514.4, Helicopter – category 6 (3.75 Grms) and Ground Mobile – category 8 (3.15 Grms).

* **Note:** See page 5-3 for information on caring for batteries.

Physical Characteristics

Height:	10.7 cm (4.2 in)
Width:	20.3 cm (8.0 in)
Depth:	24.1 cm (9.5 in), excluding handle
Weight:	2.0 kg (4.5 lb) with CHARGE-PAK and electrodes

Accessories

CHARGE-PAK Battery Charger

Type:	Li/SO_2Cl_2 Lithium Sulfuryl Chloride, 11.7V, 1.4 amp-hours.
Replacement:	Replace after each patient use or when CHARGE-PAK indicator is visible (typically after 2 years)
Weight:	80.5 grams (0.18 lb)

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QUIK-PAK Electrode Pads

Pads:	Pacing/defibrillation/ECG electrodes.
Pads Packaging:	User-intuitive, rapid-release QUIK-PAK electrodes allow the electrode pads to be pre-connected to the device and protected under a top cover.
Pads Shelf Life:	Two years typical.
Electrode Shape:	Oval-rectangular.
Electrode Size:	11.2 cm (4.4 in) × 18.5 cm (7.3 in)
Lead Wire:	1.067 meters (3.5 feet)
Conductive Adhesive Gel Contact Area:	82 cm^2 (12.8 in^2)
Maximum Adhesion Time:	24 hours
Maximum ECG Monitoring Time:	24 hours
Maximum Number of Defibrillation Pulses:	50 at 360 joules
Maximum Pacing Duration:	Up to 12 hours

ECG is received from disposable defibrillation electrodes, standard placement (anterior-lateral).

Data Storage

Memory Type:	Internal digital memory.
ECG Storage:	Dual patient Data Storage. Minimum 20 minutes of ECG stored for the current patient. Summarized data stored for the previous patient.
Report Types:	Continuous ECG—A continuous patient ECG report. Summary—A summary of critical resuscitation events and ECG waveform segments associated with these events. Event Log report—A report of time stamped markers, which reflect operator and device activity. Test Log report—A device self test activity report.
Capacity:	Minimum 200 time stamped Event Log markers.
Communications:	Wireless transfer to a personal computer.
Data Review:	Medtronic provides an array of tools to meet customer needs for data viewing and analysis.

CLINICAL SUMMARY: DEFIBRILLATION OF VENTRICULAR FIBRILLATION AND VENTRICULAR TACHYCARDIA

Background

Medtronic conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200 J and 130 J BTE shocks to 200 J MDS shocks[1] was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks (95UCLD=2%). The difference is success rates of 200 J MDS minus 200 J BTE shocks was -10% (exact 95% confidence interval from -27% to 4%). The 130 J BTE shocks were not demonstrated equivalent to 200 J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200 J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	61/68 (90%)	80 to 96%
200 J BTE	39/39 (100%)	91 to 100%
130 J BTE	39/47 (83%)	69 to 92%

Ventricular Tachycardia

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

[1] S.L. Higgins et al., "A comparison of biphasic and monophasic shocks for external defibrillation," *Prehospital Emergency Care*, 2000, 4(4):305-13.

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Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	26/28 (93%)	77 to 99%
200 J BTE	22/23 (96%)	78 to 100%
130 J MDS	20/21 (95%)	77 to 100%

Conclusions

In this double-blinded study, the efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130 J biphasic and 200 J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200 J monophasic shocks, 200 J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.

APPENDIX B
SHOCK ADVISORY SYSTEM

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OVERVIEW OF THE SHOCK ADVISORY SYSTEM

The Shock Advisory System (SAS) is an ECG analysis system built into the LIFEPAK CR Plus Defibrillator that advises the operator if it detects a shockable or nonshockable rhythm. This system makes it possible for individuals not trained to interpret ECG rhythms to provide potentially-lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The SAS contains the following features:

- Electrode contact determination
- Automated interpretation of the ECG
- Operator control of shock therapy
- Motion detection

Electrode Contact Determination

The patient's transthoracic impedance is measured through the defibrillation electrodes. If the baseline impedance is higher than a maximum limit, it is determined that the electrodes are not in sufficient contact with the patient or not properly connected to the defibrillator. ECG analysis and shock delivery are inhibited. The operator is advised to connect electrodes any time electrode contact is inadequate.

Automated Interpretation of the ECG

The Shock Advisory System is designed to recommend a shock if it detects the following:

- **Ventricular fibrillation** — with a peak-to-peak amplitude of at least 0.08 mV
- **Ventricular tachycardia** — defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. The SAS is designed to recommend no shock for all other ECG rhythms including pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, and normal sinus rhythms.

ECG analysis is performed on consecutive 2.7 second segments of ECG. The analysis of two out of three segments must agree before a decision (SHOCK ADVISED or NO SHOCK ADVISED) is made.

The LIFEPAK CR Plus Defibrillator SAS performance for adult, pacemaker and pediatric ECGs is summarized in the following table.

Table B-1 LIFEPAK CR Plus Defibrillator SAS Performance Table for Adult ECGs

Rhythm Class	ECG Test[1] Sample Size	Performance Goal[2, 3]	Observed Performance Sensitivity or Specificity [LCL][4]
Shockable: coarse VF	168	>90% sensitivity	100.0% [98.6%]
Shockable: shockable VT	65	>75% sensitivity	84.6% [77.3%]
Nonshockable: NSR	144	>99% specificity for NSR (AHA)	100.0% [98.4%]

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Table B-1 LIFEPAK CR Plus Defibrillator SAS Performance Table for Adult ECGs (Continued)

Rhythm Class	ECG Test[1] Sample Size	Performance Goal[2, 3]	Observed Performance Sensitivity or Specificity [LCL][4]
Nonshockable: asystole	43	>95% specificity	100.0% [94.8%]
Nonshockable: all other rhythms	531	>95% specificity	95.9% [94.5%]
Intermediate: fine VF	29	Report only	96.6% [87.2%] sensitivity

[1] From Medtronic ECG database. Each sample is run 10 times asynchronously.

[2] Association for the Advancement of Medical Instrumentation. DF39-1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators. Arlington, VA: AAMI;1993.

[3] Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation, 1997, Vol. 95, 1677-1682.

[4] LCL = 90% exact one-sided lower confidence limit

VF = ventricular fibrillation

VT= ventricular tachycardia

NSR = normal sinus rhythm

The LIFEPAK CR Plus Defibrillator was also tested using paced rhythms recorded at high-fidelity from patients with implanted pacemakers. The high-fidelity pacemaker spikes were also added to samples of ventricular fibrillation to test the device's ability to reach a shock decision in the case of ventricular fibrillation with an implanted, active pacemaker. The results are summarized in Table B-2.

Table B-2 LIFEPAK CR Plus Defibrillator SAS Performance with Active Pacemakers

Rhythm Class	ECG Test Sample Size	Performance Goal	Observed Performance
Shockable: Coarse VF	35	>90% sensitivity	91.4% [81.9%]
Nonshockable: Paced rhythms	35	>95% specificity	100.0% [93.6%]

The LIFEPAK CR Plus Defibrillator was also tested using ECGs acquired from hospitalized pediatric patients ranging in age from < 1 day old to 17 years old. The results are summarized in Table B-3.

Table B-3 LIFEPAK CR Plus Defibrillator SAS Performance Table for Pediatric ECGs

Rhythm Class	ECG Test[1] Sample Size	Performance Goal[2]	Observed Performance Sensitivity or Specificity [LCL][3]
Shockable: coarse VF	90	>90% sensitivity	100.0% [97.5%]
Shockable: shockable VT	11	>75% sensitivity	54.5% [31.8%]
Nonshockable: NSR	424	>99% specificity	100.0% [99.5%]
Nonshockable: asystole	95	>95% specificity	100.0% [97.6%]

Rhythm Class	ECG Test[1] Sample Size	Performance Goal[2]	Observed Performance Sensitivity or Specificity [LCL][3]
Nonshockable: all other rhythms	433	>95% specificity	99.3% [98.5%]
Intermediate: fine VF	4	Report only	100.0% [56.2%] sensitivity
Intermediate: other VT	7	Report only	42.9% [17.0%] specificity

[1] From Medtronic ECG database.

[2] Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation, 1997, Vol. 95, 1677-1682.

[3] LCL = 90% exact one-sided lower confidence limit.

Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shockable rhythm is detected, the defibrillator automatically delivers a shock or instructs the user to deliver the shock by pressing the shock button.

Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK CR Plus Defibrillator. MOTION DETECTION can be configured to be ON or OFF.

Motion can be caused by CPR, rescuer movement, patient movement, vehicle movement, or other causes. If variations in the transthoracic impedance signal exceed a maximum limit, it is determined that patient motion of some kind is present. If motion detection is ON, ECG analysis is inhibited until the motion ceases. The operator is advised any time motion is detected during an analysis by audible prompts and alert tones. If the motion does not cease within 20 seconds, analysis attempts will stop until the movement stops.

There are two reasons why ECG analysis is inhibited when motion is detected:

- Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized and, therefore, nonshockable rhythm.
- The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

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APPENDIX C
DECLARATION OF CONFORMITY

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CE 0123

EC DECLARATION OF CONFORMITY

Medtronic

Manufacturer's Name:	**Medtronic Emergency Response Systems, Inc.**
Manufacturer's Address:	**11811 Willows Road NE** **Redmond, WA 98052-2003 USA**

declares that the CE-marked product

Product Name:	LIFEPAK CR® Plus Defibrillator
Part Number(s):	3200731

complies with 93/42/EEC (Medical Device Directive) class IIb. Conformity assessed per Annex II.

This product complies with:

Safety:	EN 60601-1:1996 Internally powered, Type BF, Continuous operation IEC 60601-2-4:1983	
EMC:	EN60601-1-2:1993	
	EN 55011:1991	– Class B, Group 1
	EN 61000-4-2 1st edition	– 8kV CD, 15kV AD
	EN 61000-4-3 1st edition	– 3 V/m
	EN 61000-4-4 1st edition	– Not applicable
	IEC61000-4-5/EN 61000-4-5 1st edition	– Not applicable

Supplementary Information

Included are the following accessories and interconnecting cables:

QUIK-PAK™ electrode set, PN 3200727
Lithium CHARGE-PAK™, PN 3200730
Replacement kit, PN 3201616
Infant/Child Reduced Energy Defibrillation Electrodes, PN 3202380

This product also complies with: UL 2601-1:1994,
CSA C22.2 No. 601.1 and CSA C22.2 No. 601.2.4

Michael D. Willingham

Redmond, October 25, 2004 **Vice President, Regulatory Affairs**

This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

Authorized EC Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands

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APPENDIX D
USER'S CHECKLIST

This User's Checklist may be reproduced.

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LIFEPAK CR® PLUS DEFIBRILLATOR
USER'S CHECKLIST

Medtronic

Unit Serial Number _____

Department/Location _____

Instruction	Recommended Corrective Action	Date							
		Initials							
1 Check readiness display for:									
OK indicator	None.								
CHARGE-PAK indicator	Replace CHARGE-PAK™ and QUIK-PAK™ electrode packet.								
ATTENTION indicator	Refer to operating instructions.								
WRENCH indicator	Contact authorized service personnel.								
2 Check Use By date on QUIK-PAK electrode packet.	Replace electrode packet and CHARGE-PAK if date passed.								
3 Check additional supplies.	Replenish as needed.								
4 Check defibrillator for:									
Damage or cracks	Contact authorized service personnel.								
Foreign substances	Clean the device.								
5 Other:									

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Medtronic

!USA Device Tracking

The U.S. Food and Drug Administration classifies defibrillators as a medical device that requires tracking (knowing where the device is located). As such, federal regulations require that manufacturers maintain tracking information for each device distributed. We rely on our customers to provide accurate device location information. This tracking information provides the manufacturer the ability to locate the device and perform a product correction, should it ever be needed.

Tracking information must specify the physical location of the device, not just the headquarters or receiving department's shipping address. The tracking information required is:

1 Customer name and department name

2 Physical address (actual physical location, for example, 123 Main Street, Third Floor, Suite A)

3 City, State, and Zip Code

4 A contact name and telephone number

5 Device part number and serial number

The address to which this particular device was shipped is the current tracking location. If this device is located somewhere other than the shipping address, or if you have purchased this device from someone other than Medtronic, please either call our device tracking coordinator at 1.800.426.4448, or use one of the postage-paid address change cards below to update this vital information.

Device Tracking Change Information

1 Customer Name / Department Name

2 Physical Address (Please, no PO Box numbers)

3 City / State / Zip

4 Contact Name / Telephone Number

5 Device Part Number / Serial Number

Device Tracking Change Information

1 Customer Name / Department Name

2 Physical Address (Please, no PO Box numbers)

3 City / State / Zip

4 Contact Name / Telephone Number

5 Device Part Number / Serial Number

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL

FIRST CLASS PERMIT NO. 64 REDMOND, WA

Postage will be paid by addressee

Device Tracking Coordinator
MEDTRONIC
P. O. Box 97006
Redmond, WA 98073-9706

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL

FIRST CLASS PERMIT NO. 64 REDMOND, WA

Postage will be paid by addressee

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MIN 3201686-008 / CAT 26500-001361